IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

OUTSOURCING FACILITIES ASSOCIATION; NORTH AMERICAN CUSTOM LABORATORIES, LLC, D/B/A FARMAKEIO SUPERIOR CUSTOM COMPOUNDING, et al. Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; SARA BRENNER, in her official capacity as Acting Commissioner of Food and Drugs, 10903 New Hampshire Ave., Silver Spring, Maryland 20903 Defendants,	Civil Action No. 4:25-cv-174

COMPLAINT

Plaintiffs Outsourcing Facilities Association ("OFA") and North American Custom Laboratories, LLC, doing business as FarmaKeio Superior Custom Compounding ("FarmaKeio"), by and through undersigned counsel, allege as follows:

Nature of the Action

1. At issue in this case is a reckless and arbitrary decision by the Food and Drug Administration ("FDA") to deprive patients of a vital treatment for type 2 diabetes, obesity, cardiovascular disease, and other serious medical conditions. Semaglutide, an active ingredient that treats those conditions, has been provided to patients in large part through lawful drug compounding under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Compounding is the process by which a doctor, pharmacist, or licensed outsourcing facility combines, mixes, or alters

ingredients to create medicines tailored to patient needs. Congress determined that, when a drug is in short supply, compounding is an efficient, effective, and appropriate means to ensure that patient treatment can occur, notwithstanding the shortage. FDA placed semaglutide on the shortage list in 2022, and since then, patient demand has been satisfied in precisely the manner Congress contemplated: pharmacies and outsourcing facilities—including Plaintiffs and their members—have compounded semaglutide to meet a large segment of market demand.

2. But on February 21, 2025, FDA changed all that with a post to its website, abruptly depriving patients of much needed treatment and artificially raising drug prices. Arbitrarily dismissing evidence that the shortage persists, FDA removed semaglutide from the shortage list without notice-and-comment rulemaking, in contravention of its statutory directive, and without evidentiary support. Indeed, the agency *confirmed* that there remains a semaglutide shortage and that "many" patients cannot access semaglutide products. Indeed, the manufacturer of FDA-approved forms of semaglutide represented in its most recent Form 20-F SEC filing – filed on February 5, 2025, little more than 2 weeks prior to the FDA's action – that "supply constraints" and "drug shortage notifications" will continue into the foreseeable future. In spite of this and other information confirming a shortage, the FDA acted to benefit special interests, raise drug prices, and deprive much of the public access to a needed medicine.

3. If ever an agency action were arbitrary, capricious, and contrary to law, this is it. The Administrative Procedure Act (APA) secures the foundational principle that "the Government should turn square corners in dealing with the people," just as regulated parties "must turn square corners when they deal with the Government." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 24 (2020) (citations omitted). Under the APA, FDA's decision to remove a drug from the shortage list is clearly a "substantive" rule, which means a rule that establishes legal

rights and duties. Because of the profound impact of substantive rules, the APA demands that agencies undergo notice-and-comment rulemaking before promulgating them: an agency must propose and give notice of its action in the Federal Register, solicit comments from interested parties, and in its final decision explain its rationale and address the meaningful comments it receives in a reasoned and transparent decision. Agencies across the massive federal bureaucracy do these things every day of the week, as they must. But FDA skipped past every single requirement of reasoned rulemaking when it declared the semaglutide shortage resolved—thereby depriving patients of access to the compounded drug. This Court's immediate intervention is essential to protect the many patients who rely on compounded semaglutide and vindicate Congress's insistence on reasoned, informed rulemaking by federal agencies.

Parties

4. Plaintiff Outsourcing Facilities Association ("OFA") is a trade association based in Fort Worth, Texas, that represents outsourcing facilities that engage in drug compounding under federal law, including facilities that compound semaglutide. As explained below, all OFA members will be prohibited from compounding semaglutide by the final agency action challenged in this case. OFA's mission is to represent and advocate for the interests of outsourcing facilities and to educate the public and policymakers about the essential services and products provided by outsourcing facilities.

5. Plaintiff North American Custom Laboratories, LLC, doing business as FarmaKeio Superior Custom Compounding ("FarmaKeio"), is a Texas limited liability company headquartered in Southlake, Texas. FarmaKeio has been compounding semaglutide in compliance with federal law, and its compounding activities are directly regulated by FDA. FDA's final agency action in this case restricts semaglutide compounding by FarmaKeio, as explained below.

6. Defendant FDA is a federal agency of the United States Government headquartered in Silver Spring, Maryland. It is an agency for purposes of the APA and is subject to its requirements.

7. Defendant Sara Brenner is the Acting Commissioner of Food and Drugs and is named in her official capacity only.

Jurisdiction and Venue

8. This Court has jurisdiction over Plaintiffs' APA causes of action under 28 U.S.C. § 1331. Through the APA, the United States has waived sovereign immunity from this lawsuit. *See* 5 U.S.C. § 702.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because Plaintiffs FarmaKeio and OFA reside in this district, as do certain members of Plaintiff OFA, and a substantial part of the events or omissions giving rise to the claim occurred in this district, where FDA's final action is directly regulating Plaintiff FarmaKeio and OFA members and prohibiting activity that was theretofore lawful.

Factual and Legal Background

Congress Identifies Compounding as an Effective, Efficient, and Appropriate Means of Meeting Patient Need and Market Demand During Drug Shortages

10. "Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," typically one that is "not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Compounding "is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Id.* at 361 (internal citation omitted). "Many States specifically regulate compounding

practices as part of their regulation of pharmacies," and "[s]ome require all licensed pharmacies to offer compounding services." *Id.*

11. Congress regulated drug compounding in two provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), Section 503A, 21 U.S.C. § 353a, and Section 503B, 21 U.S.C. § 353b.

12. Section 503A regulates pharmacy compounding. Compounding that meets the requirements of this section is exempted from the FDCA's new-drug approval requirement, as well as certain drug-adulteration and branding standards. 21 U.S.C. § 353a(a). To qualify for Section 503A treatment, a drug must, *inter alia*, be compounded "on the prescription order for [an] individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs" or, if it occurs "before the receipt of a valid prescription order for such individual patient," it must be "based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product." *Id.* § 353a(a)(2)(A) and (B).

13. Section 503A authorizes compounding from "bulk drug substances," which are active ingredients typically of FDA-approved drugs, so long as the pharmacy "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product." *Id.* § 353a(b)(1)(D).

14. Section 503B establishes a separate regime governing "outsourcing facilities" that may compound drug products not based on existing prescriptions or a history of prescriptions if numerous requirements are satisfied. *Id.* § 353b. Section 503B subjects outsourcing facilities to registration, inspection, and reporting requirements and other regulations, *see id.* § 353b(a)(1) and (b), and exempts from the new-drug approval process and other FDCA requirements "a drug

compounded…in a facility that elects to register as an outsourcing facility if each of" 11 conditions are met, *id.* § 353b(a).

15. Central to the compounding regulations of Sections 503A and 503B is the drug shortage list required by Section 506E. That section requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." *Id.* § 356e(a). The provision requires that FDA identify for "each drug on such list" "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the Secretary." *Id.* § 356e(b)(1)–(4).

16. A separate provision of the FDCA defines the term "drug shortage" to mean "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c(h)(2). However, this definition does not apply by its own terms to Section 506E and does not purport to restrict the scenarios of shortage cognizable under Section 506E to those where a manufacturer's own supply does not meet national demand for an identified time period. To the contrary, Section 506E identifies various scenarios of shortage, including based on "[d]elay in shipping of the drug," *id.* § 356e(b)(3)(F), that do not turn on manufacturer supply or national demand.

17. Section 506E does not identify procedures FDA must comply with in removing a drug from the shortage list and does not displace default provisions of the APA governing FDA action in removing drugs from the shortage list.

18. When a drug is on the shortage list, Section 503A pharmacies and Section 503B outsourcing facilities are permitted to engage in compounding from its active ingredients that is unlawful if the drug is not listed on the shortage list.

19. Under Section 503B, compounding from bulk drug substances (i.e., active ingredients) is impermissible unless "the drug compounded from such bulk drug substance appears on the drug shortage list…at the time of compounding, distribution, and dispensing" or, alternatively, the bulk drug substance appears on a separate list of ingredients for which there is a "clinical need." *Id.* § 353b(a)(2)(A)(ii). FDA has narrowly construed the "clinical need" path to bulk-drug compounding, such that an FDA-approved drug not in shortage will virtually never meet the clinical-need standard. *See Athenex Inc. v. Azar*, 397 F. Supp. 3d 56 (D.D.C. 2019). As a result, FDA will typically consider bulk drug compounding from the active ingredients of an FDA-approved drug unlawful, unless the drug is listed on the shortage list.

20. A drug's listing on the shortage list carries a second, independent consequence under Section 503B. That section bars compounding of any kind of a drug that is "essentially a copy of one or more approved drugs." 21 U.S.C. § 353b(a)(5). But the statutory definition exempts from the definition of "essentially a copy of an approved drug" any drug that "appears on the drug shortage list…at the time of compounding, distribution, and dispensing." *Id.* § 353b(d)(2)(A). Consequently, if a drug appears on the shortage list, compounding of the drug will be permitted, even if it results in a drug that is essentially a copy of the FDA-approved drug. Otherwise, essential-copy compounding is unlawful, even if the active ingredient appears on the clinical-need list.

21. The effect of a drug-shortage listing is similar under Section 503A. As noted, compounding "in inordinate amounts" of "any drug products that are essentially copies of a commercially available drug product" does not qualify for protection under Section 503A. *Id.* § 353a(b)(1)(D). But FDA reads the term "commercially available drug product" not to include drugs listed on the shortage list, since such drugs are by definition not commercially available. *See*

Food and Drug Administration, Compounding when Drugs are on FDA's Drug Shortages List, https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list. As a result, Section 503A pharmacies may compound essential copies of FDA-approved drugs that are on the shortage list.

22. FDA treats drug compounding that does not meet the standards of Section 503A or 503B as a violation of the FDCA. Violations are subject to penalties. *See* 21 U.S.C. § 331(d) (prohibited acts); 21 U.S.C. § 332(1) (injunctions); 21 U.S.C. § 333 (penalties); 21 U.S.C. § 335a (debarment). Accordingly, listing of a drug on the shortage list marks the difference between a lawful business enterprise and a federal-law violation.

23. This scheme reflects a decidedly patient-focused orientation of compounding restrictions under the FDCA and, specifically, Congress's considered judgment that compounding by pharmacies and outsourcing facilities is an efficient and effective means of ensuring patient needs are satisfied when an FDA-approved drug is in shortage.

FDA Abruptly Declares Victory Over a Drug Shortage That Manifestly Persists Without Notice, Opportunity to Comment, or a Reasoned Decision

24. Semaglutide is the active ingredient in FDA-approved prescription drugs used for the treatment of type 2 diabetes, obesity, cardiovascular disease, and other serious medical conditions. The forms of semaglutide at issue in this case are administered via subcutaneous (i.e., under-the-skin) injections and are sold under the brand names Ozempic and Wegovy.

25. Wegovy has been proven effective in treating weight loss in particular, and, given the prevalence of this condition nationwide, the drug is in exceptionally high demand.

26. FDA listed Wegovy on the Section 506E shortage list in March 2022, and it listed Ozempic in August 2022.

27. The listing enabled pharmacies and outsourcing facilities to satisfy demand and patient needs through drug compounding, including compounding of drugs that are essentially copies of FDA-approved versions of semaglutide.

28. Numerous pharmacies and outsourcing facilities compounded semaglutide under Sections 503A and 503B. From that point, a large portion of market demand and patient need nationwide was satisfied by compounded forms of semaglutide lawfully produced as Congress envisioned. A conservative estimate presented to FDA showed that 2 million patients in the United States were served with compounded versions of semaglutide from November 2023 to November 2024. By comparison, the manufacturer of Wegovy asserted that it was treating 1.2 million patients with Wegovy as of early February 2025. Compounders were serving as much or more of the patient demand as the manufacturer was serving during the FDA-declared shortage.

29. In fact, notwithstanding this effort, even after the FDA listing, demand for semaglutide continued to go unsatisfied or saw delays in satisfaction. Patient needs have in this entire timeframe gone unmet due to an ongoing shortage.

30. Various industry participants communicated with FDA, providing updates with evidence of extremely high demand for semaglutide, scarcity in various regions and at the national level, and delays in filling prescriptions. For the entire period during which FDA announced a shortage of semaglutide, the agency was in actual or constructive receipt of information demonstrating that supply continued to lag behind demand, even at stark levels. On information and belief, additional information was available to FDA demonstrating that supply continued to lag behind demand but was not considered because FDA failed to engage in a meaningful inquiry.

31. Despite the ongoing shortage, FDA abruptly announced on February 21, 2025, that the shortage of semaglutide was resolved (the "Delisting Action").

32. FDA provided no notice of the Delisting Action before it took legal effect (i.e., before the effectuation of delisting occurred). Market participants did not know before that moment that compounding activities they were currently undertaking in reliance on the listing would become unlawful.

33. FDA provided no opportunity for public comment on whether to delist semaglutide.

34. By foregoing the public notice-and-comment process, FDA deprived regulated parties and other interested persons of the opportunity to comment on the proposed delisting of semaglutide and to provide probative information concerning the drug's availability. At the same time, FDA deprived itself of valuable information that would have been made available to it had the agency solicited public comment.

35. FDA resolved the semaglutide shortage even as this Court considered in a related case whether FDA may utilize notice-and-comment rulemaking before removing a drug from the shortage list and whether FDA's approach to the question of shortage is legally and factually supportable. *Outsourcing Facilities Ass'n et al., v. FDA et al.*, No. 4:24-cv-953 (N.D. Tex.). An agency exhibiting due regard for law would have awaited the Court's forthcoming ruling before engaging in a similar delisting action to ensure its acts complied with law. FDA deliberately chose action to harm millions of patients without the benefit of this Court's ruling.

36. FDA contends that the Delisting Action is not a substantive rule but the product of informal adjudication. That is not so. The Delisting Action is generally applicable and affects the rights of thousands of compounding pharmacies and outsourcing facilities. None of those persons were "parties" to FDA's supposed adjudication. The Delisting Action is prospective, not retrospective, in nature: it declares rights and prohibitions going forward and does not make

findings as to the lawfulness of action already taken. FDA therefore had no prerogative to employ information adjudication when the APA demands notice-and-comment rulemaking.

37. Even if the Delisting Action was the product of an adjudication, it is still invalid. FDA's creation and application of a new methodology to assess shortage status—disregarding all demand satisfied by compounded supply, dismissing all evidence of unavailability, and accepting the manufacturer's representations without verification or cross-checking—is not an adjudicatory application of an existing rule to the facts of a specific case. And FDA's reliance on adjudication instead of rulemaking constitutes an abuse of discretion because the Delisting Action bears all the hallmarks of a rulemaking.

38. The Delisting Action is also arbitrary and capricious and divorced from reasoned analysis. The Delisting Action does not address basic parameters and premises necessary to interpret and organize data from the manufacturer, including the time period FDA believed relevant, the supply available for that time period under a consistent reporting basis, or the demand for that time period under a consistent reporting basis. FDA failed to apprehend or at least address the many ways in which information by the manufacturer indicate an ongoing shortage.

39. The Delisting Action arbitrarily proposes that a shortage does not exist even if patients cannot access a drug. The Delisting Action reasons that "localized" supply disruptions are not within the national standard FDA infers from the governing statute. But inability of patients across the nation to obtain a product is a national problem, not a local problem. The Delisting Action irrationally fails to follow the legal standard for determining shortage status it identifies as applicable.

40. Meanwhile, FDA arbitrarily disregarded the weighty evidence that pharmacies and patients across the nation lack access to semaglutide products. Its various explanations do not

justify its treatment of the evidence but rather betray a lack of evenhandedness and effort to achieve a predetermined outcome. FDA credited undisclosed evidence of the manufacturer, but that evidence could not have credibly showed the end of the shortage because manufacturer representatives have informed their own shareholders that supply constraints and shortage persist.

41. FDA also discounted evidence that compounded semaglutide is meeting market demand to a degree that the manufacture likely could not sustain if compounded products are banned and/or restricted. As noted, evidence before FDA showed that dispensed quantities of compounded forms of semaglutide rival or even exceed the supply of the manufacturer. FDA erroneously treated this demand as legally irrelevant, proposing that purchasers of compounded forms will simply drop out of the market once those forms become unavailable, since they are generally less expensive than the manufacturer's products. Simply put, FDA determined that the shortage list is meant to protect profits of large pharmaceutical corporations and that shortages are best resolved by deeming Americans of modest or low means as not within the legal definition of "demand." FDA also made plain factual errors in assessing supply and demand.

Plaintiffs Are Stifled in Their Efforts to Ensure Patients Receive Important Treatments at Reasonable Prices

42. Plaintiff FarmaKeio is a compounding pharmacy in Southlake, Texas that operates under Section 503A.

43. FarmaKeio compounds semaglutide pursuant to Section 503A and in reliance on semaglutide's drug-shortage status. With semaglutide removed from the shortage list, FarmaKeio will be unable to continue accepting prescriptions for semaglutide and filling them with compounded semaglutide. FarmaKeio would continue accepting prescriptions and filling them with compounded semaglutide but for FDA's action.

44. Plaintiff OFA is a trade association representing outsourcing facilities registered under Section 503B, including in this judicial district. All members of OFA are outsourcing facilities that compound drugs within the Section 503B framework. Because FDA removed semaglutide from the shortage list, and because semaglutide is not on the clinical need list, bulk compounding of semaglutide will be categorically unavailable under Section 503B and thus prohibited to all OFA's members.

45. The compounded drugs produced by FarmaKeio and OFA's members help meet patient needs, fulfill market demand, and keep prices down.

46. Compounding by an outsourcing facility under Section 503B is expensive. OFA's members spent significant sums in sunk costs to support compounding operations. It can cost hundreds of thousands of dollars and takes months of lead-in effort to begin compounding in compliance with Section 503B. Additionally, an outsourcing facility experiences opportunity cost from compounding operations, as manufacturing lines are devoted to compound a drug (here, semaglutide) that can no longer be put to that use after the drug is removed from the list. It takes additional investment and time before the same manufacturing lines can be converted to other uses.

47. FDA's Delisting Action will (if it stands) cause OFA's members to fail to capitalize on their investment. It will destroy their revenues, and those of FarmaKeio, from the sale of compounded drugs that are in acute demand. Even if Plaintiffs prevail in this action, they will be unable to recoup lost revenues or profits from the federal government.

48. OFA's members and FarmaKeio intend to continue compounding semaglutide on a prospective basis to continue meeting patient needs and market demand and would do so but for FDA's arbitrary and unlawful removal of semaglutide from the shortage list.

49. OFA's members invested in technology, equipment, space, human resources, and other assets in order to facilitate compounding semaglutide. Without court intervention or further action by FDA, these investments will be wholly or partially impaired or adversely impacted.

50. The shortage of semaglutide continues. Without lawful compounding under Sections 503A and 503B, patient needs will not be fulfilled and market demand will not be satisfied. Conditions treated by semaglutide will go untreated, resulting in further disease and increased mortality rates.

FIRST CAUSE OF ACTION
(Agency Rulemaking Without Requisite Notice, Comment, and Explained Decision)

51. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

52. The APA establishes a notice-and-comment rulemaking requirement that applies to all agency rulemaking, with limited exceptions that do not apply here. 5 U.S.C. § 553.

53. Under the notice-and-comment process, an agency must issue a notice of proposed rulemaking in the Federal Register with specified information (e.g., legal authority for the rule, description of the rule), solicit public comments for a period not less than 30 days, and review those comments. An agency must also respond to meaningful comments in its final rulemaking.

54. The Delisting Action is final agency action that qualifies as an agency rule. A "rule" is defined to include "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). "[T]he APA defines the term 'rule' broadly enough to include virtually every statement an agency may make." *Apter v. Dep't of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023). FDA's Delisting Action meets this definition.

55. FDA's Delisting Action is a "legislative" rule that is subject to the notice-and-comment requirement because it "has the force and effect of law." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Listing and removal mark the difference between a lawful compounding business enterprise and one FDA considers unlawful and subject to severe penalties. Accordingly, a delisting decision is a rule "affecting individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979).

56. FDA's Delisting Action is not eligible for the exemption from notice-and-comment requirements applicable to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). FDA's Delisting Action is not interpreting a legal provision, making a generic policy statement, or governing the agency's internal process. Rather, a delisting decision declares previously lawful activity, regarded by Congress as beneficial, to be unlawful.

57. No provision of the FDCA "expressly" exempts FDA from the APA's notice-and-comment requirement, as is necessary for an organic statute to eliminate such a requirement. 5 U.S.C. § 559.

58. FDA's Delisting Action is not the product of adjudication. Even if the delisting action is regarded as adjudication, FDA abused its discretion in utilizing adjudication for a matter subject to the notice-and-comment-rulemaking requirement.

59. FDA did not engage in notice-and-comment rulemaking before issuing its final decision removing semaglutide from the shortage list.

60. FDA's final decision removing semaglutide from the shortage list is therefore "contrary to law" and "without observance of procedure required by law" under the APA and must

be "set aside." 5 U.S.C. § 706(2)(A), (D). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SECOND CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Omission of Rationale Sufficient to Explain Final Agency Action)

61. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

62. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. This standard obligates an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Because the agency's disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation, a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Regents of the Univ. of California*, 591 U.S. at 16.

63. FDA's sole basis for final action removing semaglutide from the shortage list was its reliance on data provided by the manufacturer of brand-name semaglutide products. But that data could not have established the shortage resolved where the manufacturer's public statements indicate a shortage.

64. FDA's decision—the sole basis on which the Delisting Action could be upheld—says nothing of key parameters necessary to determine whether supply satisfies demand for any given time period. The decision does not identify what time period it considers relevant or how supply and demand are properly reported. Nor does FDA provide any comparison between the

time period for which the shortage was declared resolved and the time period when the shortage was first declared.

65. FDA's final decision removing semaglutide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

THIRD CAUSE OF ACTION
(Lack of Reasoned Decisionmaking by Arbitrary and Facially Contradictory Findings That Refute or Undermine the Basis of Final Agency Action)

66. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

67. The APA obligates agencies to engage in reasoned decisionmaking and directs that their actions be set aside if arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 16 (2020). This includes requirements that agencies consider relevant factors and provide an explanation for their final actions. *Id.* at 16, 20–24. Because the agency's disclosed bases for a final action supply the sole grounds on which it may be upheld in litigation, a failure to provide sufficient grounds for the decision, standing alone, requires vacatur of the decision and remand. *Id.* at 20–24.

68. A corollary of these principles demands that agency determinations be founded on findings that are not themselves arbitrary and capricious. This principle forbids agencies to predicate their actions on determinations that are facially incoherent or inconsistent.

69. FDA's final decision removing semaglutide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FOURTH CAUSE OF ACTION
(Arbitrary and Capricious Determination That Semaglutide Shortage Ended)

70. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

71. The APA forbids arbitrary and capricious agency action.

72. FDA acted arbitrarily and capriciously in determining that the drug shortage has ended in the face of overriding evidence that supply of semaglutide—including supply made possible by compounding—cannot keep pace with demand.

73. Market participants presented FDA evidence that patient needs and market demand for semaglutide is not satisfied by current supply, including supply made possible by compounding. Additional evidence was available to FDA that patient needs and market demand for semaglutide is not satisfied by current supply, including supply made possible by compounding, had it engaged in appropriate investigation. Information provided by the manufacturer, properly interpreted, lent further support to evidence showing an ongoing shortage.

74. FDA, however, rushed out a decision declaring the shortage had ended based solely (or primarily) on statements by the manufacturer that it can meet demand, despite substantial probative evidence proving to the contrary, including the manufacturer's own evidence.

75. FDA's final decision removing semaglutide from the shortage list is therefore "arbitrary and capricious" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

FIFTH CAUSE OF ACTION
(Unlawful Interpretation and Application of Drug Shortage Statute)

76. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

77. Agency action must comply with the law Congress imposed on that agency. Agency obligations under a statute are resolved through court determination of "the best reading of the statute" without deference to the agency. *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2266 (2024).

78. FDA's decision rests on an erroneous reading of statutes. The FDCA requires FDA to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). This provision enumerates various circumstances where a shortage may arise, including a "[d]elay in shipping of the drug." *Id.* § 356e(b)(3)(F).

79. FDA, however, looked to a different provision of the FDCA, addressing manufacturer shortage reporting for its definition of a shortage. *Id.* § 356c(h)(2). That section, however, defines "drug shortage" only "[f]or purposes of this section." *Id.* § 356c(h)(2). It does not purport to define the full scope of shortages or causes of shortage.

80. FDA erred in applying this overly restrictive definition. For example, it stated that it would ignore inability of patients to obtain semaglutide without proof of a nationwide shortage and that it would not treat supply chain disruptions as evidence of a shortage if wholesalers had not entirely run out of semaglutide products. Nothing in Section 506E supports those determinations.

81. Additionally, FDA stated that it would not consider portions of the demand satisfied by ongoing compounding as part of the relevant demand on the basis that (1) only demand for the brand-name (not compounded) product qualifies and (2) recipients of compounded products may drop out of the market entirely after compounded products are banned or restricted, given the high prices of brand-name semaglutide products. But shortage listing authorizes compounding of drugs that are "essentially a copy" of approved drugs. 21 U.S.C. § 353b(a)(5); *see also id.*

§ 353a(b)(1)(D). Moreover, the point of allowing essentially-a-copy compounding during shortages is to enable compounded drugs to fill the demand the manufacturer is not satisfying. Because supply and demand always meet at price, this approach redefines demand as coterminous with Lilly's supply. This would defeat the purpose of a supply-demand inquiry.

82. FDA's final decision removing semaglutide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

SIXTH CAUSE OF ACTION
(Unlawful Failure to Publish Decision in the Federal Register)

83. The above paragraphs are hereby incorporated by reference as if set forth fully herein.

84. The public information section of the APA obligates agencies to "publish in the Federal Register… (D) substantive rules of general applicability adopted as authorized by law." 5 U.S.C. § 552(a)(1)(D). This "was adopted to provide, inter alia, that administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974).

85. FDA's decision to remove semaglutide from the shortage list is a legislative rule: it affects the individual rights of numerous market participants in a generally applicable manner, as well as the interests of innumerable patients who need semaglutide for their treatment.

86. FDA did not publish its decision in the Federal Register.

87. FDA's final decision removing semaglutide from the shortage list is therefore "contrary to law" under the APA and must be "set aside." 5 U.S.C. § 706(2)(A). FDA's unlawful action entitles Plaintiffs to the relief requested below.

Prayer for Relief

Plaintiffs respectfully asks that this Court enter judgment in their favor and that they be granted the following relief:

A. Declare that FDA's final action removing semaglutide from the drug shortage list is contrary to law under the APA, which subjects that action to notice-and-comment rulemaking procedures;

B. Declare that FDA's final action removing semaglutide from the drug shortage list is arbitrary and capricious in violation of the APA;

C. Vacate and/or set aside FDA's final action removing semaglutide from the drug shortage list on the grounds stated above;

D. Permanently and temporarily enjoin FDA from taking action against Plaintiffs or their members for engaging in compounding of semaglutide that is lawful in circumstances where semaglutide is named on the drug-shortage list;

E. Award Plaintiffs their fees and costs related to this action, including reasonable attorneys' fees; and

F. Grant such other and further relief as the Court deems appropriate.

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/s/ Ty Doyle

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